

REMARKS

Applicants respectfully request reconsideration of the rejections set forth in the Final Office Action mailed on January 28, 2011.

Claims 1, 3, 14, and 78-80 had been pending and were examined. Claims 2, 4-13, and 15-77 were previously canceled without prejudice or disclaimer. Pending entry of this amendment, claims 1 and 3 are amended, and claims 14 and 78-80 are canceled without prejudice or disclaimer. Thus, with this amendment, claims 1 and 3 are pending and under consideration.

Claims 1 and 3 are amended to recite “G protein-coupled receptor protein comprising the amino acid sequence,” rather than “G protein-coupled receptor protein comprising substantially the same amino acid sequence.” Support is found in the specification, for example, at least at page 2, lines 32-35. Claims 1 and 3 are also amended to remove from step (iii) the phrase “wherein a change in cell-stimulating activity indicates that the compound or its salt changes a binding property of the G protein-coupled receptor protein.” Additionally, claims 1 and 3 are amended to correct various typographical and grammatical errors.

Claim 1 is amended to recite that the cell-stimulating activity “is at least one selected from intracellular cAMP production suppressing activity, MAP kinase phosphorylation or activation, adrenocorticotrophic hormone (ACTH) secretion suppressing activity, glycerol production suppressing activity, and lipolysis suppressing activity.” Support is found in the specification, for example, at least at page 5, lines 27-30. Claim 1 is also amended to recite “selecting the compound or its salt which changes the cell-stimulating activity.” Support is found in the specification, for example, at least at page 83, lines 19-30.

Claim 3 is amended to recite a “labeled fatty acid or a salt thereof.” Support is found in the specification, for example, at least at page 24, lines 7-16. Claim 3 is also amended to recite that the “the fatty acid is selected from palmitoleic acid, linoleic acid, γ -linolenic acid, arachidonic acid, and docosahexaenoic acid.” Support is found in the specification, for example, at least at page 52, lines 22-25. Claim 3 is further amended to recite “selecting the compound or its salt which changes the amount of binding of the G protein-coupled receptor protein.” Support is found in the specification, for example, at least at page 83, lines 19-30.

As all of these amendments are reasonably conveyed by the original claims and the specification, no new matter has been added. Applicants respectfully request entry of these claims.

Status of Application, Amendments, and/or Claims and Withdrawn Objections and/or Rejections

Applicants note with appreciation that the Examiner indicated that the second species election set forth at pages 5-6 of the September 28, 2009, Office Action is currently moot. Applicants also note with appreciation the withdrawal of the objections and rejections as outlined by the Examiner on page 2 of the Office Action.

Rejection of claims 1, 3, 14, and 78-80 under 35 U.S.C. § 112, 1st paragraph, enablement

Claims 1, 3, 14, and 78-80 are rejected under 35 U.S.C. § 112, 1st paragraph, because the specification allegedly “does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.” Action at 4. According to the Office, the specification does not reasonably provide enablement for “[a] method of screening a compound or its salt comprising: (i) contacting *in vitro* cells comprising a GPCR protein comprising substantially the same amino acid sequence represented by SEQ ID NO:1, wherein the GPCR protein has a GPCR function” *Id.* at 3.

However, the Office acknowledges that the specification is enabling for “[a] method of screening a compound or its salt comprising: (i) contacting *in vitro* cells comprising a GPCR protein comprising the amino acid sequence of SEQ ID NO:1” *Id.*

Applicants respectfully traverse. Nonetheless, solely to facilitate prosecution and not in acquiescence to the Office’s rejection, claims 1 and 3 are amended to recite “the amino acid sequence represented by SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 8.” As noted above, claims 14 and 78-80 are now canceled, and this rejection is moot with respect to those claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of claims 1, 3, 14, and 78-80 rejected under 35 U.S.C. § 112, 1st paragraph, written description

Claims 1, 3, 14, and 78-80 remain rejected under 35 U.S.C. § 112, 1st paragraph, for allegedly “failing to comply with the written description requirement.” Action at 6. The Office alleges that the specification “fails to describe the entire genus of polypeptides that are encompassed by each of the claims.” Action at page 7. However, the Office acknowledged that “a method of screening a compound or its salt comprising: (i) contacting *in vitro* cells comprising a GPCR protein comprising the amino acid sequence of SEQ ID NO:1 . . . meets the written description requirement.” *Id.* at 7-8.

Applicants respectfully traverse. Nonetheless, as described above with respect to the rejection regarding enablement, without acquiescence, claims 1 and 3 are amended to recite “the amino acid sequence represented by SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 8.” and claims 14 and 78-80 are canceled. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections of claims 1, 3, 14, and 78-80 under 35 U.S.C. § 102(b)

Claims 1, 3, 14, and 78-80 are rejected under 35 U.S.C. § 102(b), for allegedly being anticipated by Sidhu et al. (J. Physiol., 528(1): 165-176 (2000)) (“Sidhu”). Action at 8. The Office maintains that Sidhu teaches the application of dodecanoic acid (a fatty acid) to the enteroendocrine cell line STC-1, and states that the STC-1 cell line contains a GPCR that is 100% identical to SEQ ID NO:1. The Office also relies on Sidhu to teach a difference in Ca^{2+} response when dodecanoic acid was applied alone to STC-1 cells and when it was applied in the presence of BSA. *Id.* at 9-10. Furthermore, the Office interprets the clause reciting “wherein a change in cell-stimulating activity indicates that the compound or its salt changes a binding property of the G protein-coupled receptor,” which was previously recited in the claims, as a “mental conclusion” that “does not patentability [sic] distinguish the claimed method from any prior art method teaching[] steps (i)-(iii).” *Id.* at 9.

Applicants respectfully traverse. Sidhu does not teach each and every element of claim 1 or claim 3¹. Claim 1 is amended to recite the affirmative step of “selecting the compound or its salt which changes the cell-stimulating activity.” Furthermore, “the cell-stimulating activity is at least one selected from intracellular cAMP production suppressing activity, MAP kinase phosphorylation or activation, adrenocorticotrophic hormone (ACTH) secretion suppressing activity, glycerol production suppressing activity, and lipolysis suppressing activity.” Accordingly, claim 1 recites an affirmative step that is not simply a mental conclusion. Moreover, Sidhu does not teach anything regarding intracellular cAMP production suppressing activity, MAP kinase phosphorylation or activation, adrenocorticotrophic hormone (ACTH)

¹ As discussed above, claims 14 and 78-80 are canceled, and this rejection is now moot with respect to those claims.

secretion suppressing activity, glycerol production suppressing activity, and lipolysis suppressing activity. Instead, as recognized by the Office, Sidhu focuses on Ca^{2+} responses.

Claim 3 is amended to recite the affirmative step of “selecting the compound or its salt which changes the amount of binding of the G protein-coupled receptor protein,” which is, again, not simply a mental conclusion. Additionally, claim 3 recites a “labeled fatty acid or a salt thereof” and indicates that “the fatty acid is selected from palmitoleic acid, linoleic acid, γ -linolenic acid, arachidonic acid, and docosahexaenoic acid.” Instead of teaching the recited fatty acids, and as recognized by the Office, Sidhu discloses applying dodecanoic acid alone or in the presence of BSA to STC-1 cells.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of claims 1, 3, 14, and 78-80 under 35 U.S.C. § 112, 2nd paragraph

Claims 1, 3, 14, and 78-80 are rejected under 35 U.S.C. § 112, 2nd paragraph, as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Action at page 12. In particular claims 1 and 3 stand rejected because the antecedent basis for the term “a salt” in steps (ii) and (iii) is allegedly unclear. Applicants respectfully traverse. As amended, claims 1 and 3 recite “the fatty acid or the salt thereof.”

Additionally, claims 78-80 are rejected as allegedly lacking antecedent basis for “a G protein coupled receptor protein.” As described above, claims 78-80 are canceled, thus rendering this rejection moot.

For at least these reasons, Applicants request reconsideration and withdrawal of the rejection.

Conclusion

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 1 and 3 in condition for allowance.

It is respectfully submitted that the entry of the Amendment would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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